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10/524,195

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Ryoji Fujii

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EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/524,195

Applicant(s)

FUJII, RYOJI

Examiner

Andrew M. Gilbert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-9, 11, 12 and 14-19 is/are rejected.
- 7) ☒ Claim(s) 5, 10 and 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Acknowledgements***

1. This office action is in response to the reply filed on 2/7/2006.
2. In the reply the Applicant amended claims 1-8, 10-11, 13-15, and 19-20. Claims 20-22 are withdrawn.
3. Additionally, the Applicant filed a certified copy of the priority application JP 2002-235170, filed August 12, 2002. This fulfills the conditions of 35 USC 119(a-d) for foreign priority. As a result, the previous rejection in the office action mailed 12/1/2005 by US Pat. Pub. No. 2004/0102738 is overcome as the reference has an effective prior art date of 11/26/2002, which is subsequent to the 8/12/2002 filing date of the priority application for the present application.

### ***Drawings***

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the compression ribs provided at both side ends of the main body in the breadth direction (see Figs 4A-6B; the compression ribs are provided at both side ends of the main body in the length direction) and the inner wall of the cover forming the cavity is tapered so that the diameter of the cavity section gradually becomes *larger* from the inner end thereof toward the outer end thereof along the axis of the cavity (see Fig 1B – shows the cavity becoming *smaller* from (9) towards (3)) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Needleless Port.

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 10 recites the limitation "the diameter of the cavity section gradually becomes larger from the

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inner end thereof towards the outer end thereof..." in lns 2-3. There is insufficient antecedent basis for this limitation in the claim. See above discussion in "Drawings".

### ***Claim Objections***

7. Claim 3 is objected to because of the following informalities: Claim 3, ln 5-6 recites the limitation "a major axis of the inner-end plate is larger than an inside diameter of the internal wall of the cover". The Examiner notes that "a major axis" does not possess a physical length. It is an axis, not a length. The Examiner assumes that the Applicant meant the length of a major axis of the inner-end plate is larger than an inside diameter of the internal wall of the cover. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-2, 4, 6, 7, 18, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Atkinson et al, hereafter "Atkinson", (5533708). In reference to claim 1, Atkinson discloses a needleless port (10) comprising: a pedestal that forms a part of a flow channel (12) and has an opening to the flow channel; a cover (14) that is engaged with the pedestal at a position corresponding to the opening and has a cavity that opens to exterior (Fig 2) at a predetermined

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distance from the opening; and a septum that is held in the cavity (16) and is made of a resilient material (col 6, Ins 38-40) with a passageway for allowing an insertion member to be inserted from the exterior to the opening (Fig 3), wherein the septum comprises a main body (28) that extends from an inner end on the pedestal side toward an outer end on the exterior side of the cavity of the cover, with the passageway being formed between an inner-end face and an outer-end face thereof and compression ribs (44, 46) provided on sides of the main body the main body has a cross section in a direction orthogonal to the passageway of a shape having a dimension in a length direction larger than that in a breadth direction (Fig 4; col 7, Ins 1-35) – (NOTE: the Examiner has interpreted a shape having a dimension in a length direction larger than in a breadth direction to be any length of the shape that has a dimension in a length direction larger than in a breadth direction which can include projections and indentations; subsequently, the recitation as claimed does not necessitate the main body having an oval shape having a major and minor axis); the passageway includes a slit (36) and a bore (Fig 4, 36; Fig 10, 36'), the slit having a predetermined depth from the outer-end face of the main body and extending in the same direction as the breadth direction, and the bore extending from the slit to the inner-end face of the main body and having a lateral section of a spindle shape whose major axis extends in the same direction as the breadth direction (Figs 1-18; col 7, Ins 1-35); additionally, Atkinson discloses that compression ribs can be provided at the both side ends of the main body in the breadth direction (253; col 11; Ins 12-18) so as to extend along the axial direction of the passageway, the cavity of the cover has

a circular cross section whose diameter is smaller than a distance between the external surfaces of the compression ribs (col 7, lns 36-67), and with the septum being held inside the cavity a space is formed between an external surface of the main body at a part without the compression ribs and an internal wall of the cover, and the bore is dosed by a compressive force applied from the internal wall of the cover to the septum via the compression ribs (col 7, lns 36-67).

10. In reference to claim 2, Atkinson discloses the invention substantially as claimed in regards to claim 1, and additionally discloses a substantial passageway (36), the substantial passageway includes an unpenetrated region (36) and a bore (Fig 4, 36; Fig 10, 36'), and the compression ribs (44, 46) are provided at the both side ends of the main body in the length direction so as to extend along the axial direction of the substantial passageway (Figs 2-18).

11. In reference to claim 4, Atkinson discloses the invention substantially as claimed and additionally discloses the septum having, around an outer end of the main body, an outer-end plate that is exposed to outside of the cover and is larger in size than an inside diameter of the cover at an outer end of the cover. (38; Fig 2; 42; col 6, lns 65-67; col 7, lns 42-48).

12. In reference to claim 6, Atkinson discloses the invention substantially as claimed and additionally discloses the septum having, on an outer end thereof, a surface depression portion which is formed at a central area to be substantially level and depressed in relation to an area surrounding the central area (Fig 2; col 10, lns 16-20).

13. In reference to claim 7, Atkinson discloses the invention substantially as claimed and additionally discloses a surface of the outer-end plate is flat (Fig 13; col 10, lns 16-20).

14. In reference to claim 18, Atkinson discloses the invention substantially as claimed and additionally discloses an inner peripheral portion at an outer end of the cover is chamfered (Figs 1, 6, 13, 15).

15. In reference to claim 19, Atkinson discloses the invention substantially as claimed and additionally discloses wherein the material of the septum is a thermoplastic elastomer (col 6, lns 38-40).

***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 8-9, 11-12, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atkinson. Atkinson discloses the invention substantially as claimed except for expressly disclosing a length  $L_{sO}$  of the main body in a state in which the septum is not mounted inside the cover is smaller than a length  $L_c$  of the cover at a portion for holding the main body therein; wherein the septum being held inside the cover, an expansion ration is within a range of 5% to 40%, the expansion ration being calculated by dividing an expanded length of the septum by the length  $L_c$ ; a ratio of the distance between the external surfaces of



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the compression ribs to the inside diameter of the cover and a ratio of the length in the major axis of the inner-end plate to the inside diameter of the cover are each within a range of 1.05 to 1.4; a ratio of a dimension in the breadth direction of the main body to the inside diameter of the cover and a ratio of a minor axis of the inner-end plate to the inside diameter of the cover are each within a range of 0.8 to 1.0; a ratio of the predetermined depth of the slit to a height of the main body of the septum is within a range of 0.04 to 0.60, the predetermined depth being measured in a direction of the passageway; the predetermined depth of the slit measured in a direction of the passageway is within a range of 0.2 mm to 3.0 mm.

18. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have these recited limitations of claims 8-9, 11-12, 14-15 because the Applicant has not disclosed that the recited limitations of claims 8-9, 11-12, 14-15 provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with needless port of Atkinson because the needless port of Atkinson performs substantially the same function as the claimed invention of the Applicant. Therefore, it would have been an obvious matter of design choice to modify Atkinson to obtain the invention as specified in claims 8-9, 11-12, 14-15.

19. Claims 3, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atkinson in view of Atkinson et al (5010925). Atkinson discloses the invention substantially as claimed and additionally discloses the

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septum being held inside the cavity, a compressive force acting in the major axis direction is applied from the cover to the inner-end plate (col 7, lns 42-67; Fig 2-4); an annular rib (65) is provided around the opening of the pedestal, the annular rib projecting toward the cover, and the inner end plate of the septum is sandwiched between the internal wall of the cover and the annular rib so that the annular rib engages with a bottom surface of the inner-end plate, thereby establishing liquid tightness (Figs 2-4; col 7, lns 42-67); and the internal wall of the cover has one or more indents that are engaged with an external surface of the septum (Figs 2-4). However, Atkinson does not disclose the septum having an inner end plate that has an oval shape whose major axis extends in the same direction as the length direction of the main body.

20. Atkinson et al teaches that it is known to have the septum having an inner end plate (50) that has an oval shape (Fig 2) whose major axis extends in the same direction as the length direction of the main body (col 2, lns 29-33) for the purpose of helping to accurately position the valve opening within the outlet portion to help bias the valve lips together. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inner end plate as taught by Atkinson with the oval shape as taught by Atkinson et al for the purpose of helping to accurately position the valve opening within the outlet portion to help bias the valve lips together.

***Allowable Subject Matter***

21. Claims 5, 10, and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

22. Applicant's arguments with respect to claims 1-4, 7, 16-19 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number

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is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Andrew Gilbert

KEVIN SIRMONS  
PRIMARY EXAMINER

